DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE

COMMISSION,

Civil Action Plaintiff,

No. 05-11805-NMG

v.

JURY TRIAL DEMANDED RICHARD B. SELDEN,

Defendant.

DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSES

Defendant Richard F. Selden¹ ("Defendant"), by his undersigned counsel, answers the Complaint, upon knowledge as to himself and his own acts and otherwise upon information and belief, as follows:

Defendant denies the allegations in paragraph 1 of the Complaint, 1. except admits that Transkaryotic Therapies, Inc. ("TKT") was a bio-pharmaceutical company based in Cambridge, Massachusetts; Defendant was TKT's former CEO; TKT developed a drug known as Replagal; and refers to Defendant's Forms 4 for the complete terms and contents thereof.

Richard F. Selden is incorrectly identified as Richard B. Selden in the Complaint.

- Defendant denies the allegations in paragraph 2 of the Complaint, 2. except admits that in June 2000, TKT submitted a Biologics License Application ("BLA") with the FDA for Replagal and that TKT filed reports with the Commission, and refers to the BLA and reports for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 3 of the Complaint, 3. except admits that TKT made a public announcement after the market close on October 2, 2002, and refers to the announcement for the complete terms and contents thereof; and that on October 2, 2002, the closing price of TKT stock traded on Nasdaq was \$33.25 per share and on October 3, 2002, the closing price of TKT stock traded on Nasdaq was \$12.75 per share.
- 4. Defendant denies the allegations in paragraph 4 of the Complaint, and refers to Defendant's Forms 4 for the complete terms and contents thereof.
 - 5. Defendant denies the allegations in paragraph 5 of the Complaint.
- 6. Defendant avers that the Complaint speaks for itself and that no further answer is required as to paragraph 6 of the Complaint. To the extent a response is required, Defendant denies the allegations in paragraph 6 of the Complaint.
- 7. Defendant avers that the allegations in paragraph 7 of the Complaint are legal conclusions as to which no answer is required, except Defendant admits that TKT's corporate headquarters were in this District and that Defendant lives in this District. To the extent any further response is required, Defendant denies the allegations in paragraph 7 of the Complaint.

- Defendant avers that the Complaint speaks for itself and that no 8. further answer is required as to paragraph 8 of the Complaint. To the extent a response is required, Defendant denies the allegations in paragraph 8 of the Complaint.
 - 9. Defendant denies the allegations in paragraph 9 of the Complaint.
- Defendant denies the allegations in paragraph 10 of the Complaint, 10. except admits that Defendant founded TKT in 1988 and served as a director between 1988 and February 2003.
- Defendant denies the allegations in the first sentence of paragraph 11. 11 of the Complaint, except admits that TKT, a Delaware corporation, was a biopharmaceutical company headquartered in Cambridge, Massachusetts. Upon information and belief, Defendant admits the allegations in the second sentence of paragraph 11 of the Complaint. Defendant avers that the allegations in the third sentence of paragraph 11 of the Complaint are legal conclusions as to which no answer is required. To the extent a response is required, Defendant denies the allegations in the third sentence of paragraph 11 of the Complaint. Defendant denies knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth and fifth sentences of paragraph 11 of the Complaint.
- 12. Defendant denies the allegations in paragraph 12 of the Complaint, except admits that Replagal and Fabry disease are described in various of TKT's filings with the Securities and Exchange Commission, and refers to those filings for the complete terms and contents thereof; and avers that the allegations in the fifth sentence of paragraph 12 of the Complaint are legal conclusions as to which no answer is required.

To the extent a response is required, Defendant denies the allegations in the fifth sentence of paragraph 12 of the Complaint.

- Defendant denies the allegations in paragraph 13 of the Complaint, except admits that in June 2000, TKT submitted a BLA with the FDA for Replagal, and refers to the BLA for the complete terms and contents thereof; admits, upon information and belief, that on or about June 26, 2000, Genzyme submitted a BLA with the FDA for Fabrazyme; denies knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth, fifth and sixth sentences of paragraph 13 of the Complaint; and refers to the alleged analyst statement for the complete terms and contents thereof.
- 14. Defendant denies the allegations in paragraph 14 of the Complaint, except avers that TKT 003 is described in TKT's BLA, and refers to the BLA for the complete terms and contents thereof.
- Defendant denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 of the Complaint, except avers that the "p value" is a measure of a statistical result.
- Defendant denies the allegations in paragraph 16 of the Complaint, and refers to the BLA for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 17 of the Complaint, except admits that in May 2000, Defendant and/or other senior TKT executives met with investors; and refers to the BLA for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 18 of the Complaint, 18. except admits that in October 2000, one or more TKT executives attended a conference

sponsored by the American Society of Human Genetics ("ASHG"), at which one or more presentations were made.

- Defendant denies the allegations in paragraph 19 of the Complaint. 19.
- 20. Defendant denies the allegations in paragraph 20 of the Complaint, and refers to the alleged analyst statement for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 21 of the Complaint, except admits that on or about January 2, 2001, TKT received a complete review letter from the FDA, and refers to the letter for the complete terms and contents thereof. Defendant further avers that the allegations in the first sentence of paragraph 21 of the Complaint are legal conclusions as to which no answer is required. To the extent a response is required, Defendant denies the allegations in the first sentence of paragraph 21 of the Complaint.
- Defendant denies the allegations in paragraph 22 of the Complaint, and refers to the review letter for the complete terms and contents thereof.
- 23. Defendant denies the allegations in paragraph 23 of the Complaint, except admits that on or about January 3, 2001, TKT issued a press release, and refers to the press release for the complete terms and contents thereof; and that on or about January 3, 2001, TKT filed a current report with the Commission on Form 8-K. incorporating the press release, and refers to the report for the complete terms and contents thereof.
- 24. Defendant denies the allegations in paragraph 24 of the Complaint, except admits that on January 4, 2001, the closing price of TKT stock traded on Nasdag was \$33.25 per share; on January 3, 2001, the closing price of TKT stock traded on

Nasdag was \$36.56 per share; and avers that market reaction to the January 3, 2001, TKT press release was negative.

- 25. Defendant denies the allegations in paragraph 25 of the Complaint.
- Defendant denies the allegations in paragraph 26 of the Complaint. 26.
- Defendant denies the allegations in paragraph 27 of the Complaint, 27. except admits, upon information and belief, that on or about April 2, 2001, TKT filed with the Commission its annual report on Form 10-K, and refers to the Form 10-K for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 28 of the Complaint, and refers to the Form 10-K for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 29 of the Complaint, 29. and refers to the annual report for the complete terms and contents thereof.
- 30. Defendant denies the allegations in paragraph 30 of the Complaint, and refers to the annual report for the complete terms and contents thereof.
- 31. Defendant denies the allegations in paragraph 31 of the Complaint, except admits that on or about April 26, 2001, Defendant and several other TKT executives met with FDA staff.
 - Defendant denies the allegations in paragraph 32 of the Complaint. 32.
 - 33. Defendant denies the allegations in paragraph 33 of the Complaint.
- 34. Defendant denies the allegations in paragraph 34 of the Complaint, except admits that on or about May 14, 2001, TKT filed with the Commission its report on Form 10-Q for the quarter ended March 31, 2001, and refers to the Form 10-Q for the complete terms and contents thereof.

- Defendant denies the allegations in paragraph 35 of the Complaint, and refers to the Form 10-Q for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 36 of the Complaint, except admits that on or about May 29, 2001, TKT issued a press release, and refers to the press release for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 37 of the Complaint, 37. and refers to the press release and report for the complete terms and contents thereof.
 - Defendant denies the allegations in paragraph 38 of the Complaint. 38.
- Defendant denies the allegations in paragraph 39 of the Complaint, 39. except admits that on or about May 30, 2001, several TKT executives had a conference call with FDA staff.
- 40. Defendant denies the allegations in paragraph 40 of the Complaint, except admits that on or about June 25, 2001, TKT filed with the Commission a Form 8-K, and refers to the Form 8-K for the complete terms and contents thereof; on or about June 26, 2001, TKT filed with the Commission a prospectus supplement, and refers to the prospectus supplement for the complete terms and contents thereof; and avers that the allegations in the third sentence of paragraph 40 of the Complaint are legal conclusions as to which no answer is required. To the extent a response is required, Defendant denies the allegations in the third sentence of paragraph 40 of the Complaint.
- Defendant denies the allegations in paragraph 41 of the Complaint, 41. and refers to the Form 8-K and prospectus supplement for the complete terms and contents thereof.

- Defendant denies the allegations in paragraph 42 of the Complaint, 42. and refers to the Forms 10-Q for the complete terms and contents thereof.
- Defendant denies the allegations in paragraph 43 of the Complaint, 43. and refers to the prospectus, Form 8-K and Forms 10-Q for the complete terms and contents thereof. Defendant further avers that the allegations in the third sentence of paragraph 43 of the Complaint are legal conclusions as to which no answer is required. To the extent a response is required, Defendant denies the allegations in the third sentence of paragraph 43 of the Complaint.
- Defendant denies the allegations in paragraph 44 of the Complaint, except admits that on one ore more TKT quarterly conference calls, Defendant spoke with one or more of the participants.
 - 45. Defendant denies the allegations in paragraph 45 of the Complaint.
 - 46. Defendant denies the allegations in paragraph 46 of the Complaint.
 - 47. Defendant denies the allegations in paragraph 47 of the Complaint.
 - 48. Defendant denies the allegations in paragraph 48 of the Complaint.
- 49. Defendant denies the allegations in paragraph 49 of the Complaint, except admits, upon information and belief, that in early summer 2002, the FDA scheduled advisory committee meetings for September 26-27, 2002, in connection with Replagal and Fabrazyme; and denies knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentences of paragraph 49 of the Complaint.
- 50. Defendant denies the allegations in paragraph 50 of the Complaint, and refers to the FDA's briefing materials for the complete terms and contents thereof.

- Defendant denies the allegations in paragraph 51 of the Complaint, except admits that on or about September 11, 2002, TKT's outside attorney wrote to the FDA, and refers to that writing for the complete terms and contents thereof; and avers that advisory committee meetings were scheduled for January 13-14, 2003.
 - Defendant denies the allegations in paragraph 52 of the Complaint. 52.
- Defendant denies the allegations in paragraph 53 of the Complaint, 53. except admits that on October 2, 2002, TKT issued a press release after the Nasdaq market close, and refers to the press release for the complete terms and contents thereof.
- 54. Defendant denies the allegations in paragraph 54 of the Complaint, except admits that on October 3, 2002, the closing price of TKT stock traded on Nasdaq was \$12.75 per share; on October 2, 2002, the closing price of TKT stock traded on Nasdaq was \$33.25 per share; and that, upon information and belief, the average daily trading volume for TKT stock in September 2002 was approximately 760,000 shares.
- 55. Defendant denies the allegations in paragraph 55 of the Complaint, except admits that on or about January 14, 2003, the advisory committee panel met regarding Replagal; and admits, upon information and belief, that the FDA approved Fabrazyme for sale in the United States.
- 56. Defendant denies the allegations in paragraph 56 of the Complaint, except denies knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 56; and admits that in February 2003, Defendant resigned as CEO of TKT.
- Defendant denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 of the Complaint.

- 58. Defendant denies the allegations in paragraph 58 of the Complaint, and refers to Defendant's Forms 4 for the complete terms and contents thereof.
- 59. Defendant denies the allegations in paragraph 59 of the Complaint, and refers to Defendant's Forms 4 for the complete terms and contents thereof.
- 60. Defendant denies the allegations in paragraph 60 of the Complaint, and refers to Defendant's Forms 4 for the complete terms and contents thereof.
- 61. Defendant denies the allegations in paragraph 61 of the Complaint, and refers to Defendant's Forms 4 for the complete terms and contents thereof.
- 62. Defendant denies the allegations in paragraph 62 of the Complaint, and refers to Defendant's Forms 4 for the complete terms and contents thereof.
 - 63. Defendant denies the allegations in paragraph 63 of the Complaint.
 - 64. Defendant denies the allegations in paragraph 64 of the Complaint.
 - 65. Defendant denies the allegations in paragraph 65 of the Complaint.
 - 66. Defendant denies the allegations in paragraph 66 of the Complaint.
 - 67. Defendant denies the allegations in paragraph 67 of the Complaint.
 - 68. Defendant denies the allegations in paragraph 68 of the Complaint.
- 69. Defendant repeats and realleges his answers to paragraphs 1-68 of the Complaint as if fully set forth herein.
 - 70. Defendant denies the allegations in paragraph 70 of the Complaint.
 - 71. Defendant denies the allegations in paragraph 71 of the Complaint.
 - 72. Defendant denies the allegations in paragraph 72 of the Complaint.
- 73. Defendant repeats and realleges his answers to paragraphs 1-72 of the Complaint as if fully set forth herein.

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- Defendant denies the allegations in paragraph 74 of the Complaint. 74.
- Defendant denies the allegations in paragraph 75 of the Complaint. 75.
- 76. Defendant denies the allegations in paragraph 76 of the Complaint.
- 77. Defendant denies the allegations in paragraph 77 of the Complaint.

FURTHER, Defendant denies the allegations in the unnumbered paragraph of the Complaint beginning with the word "WHEREFORE" (including subparagraphs "A" through "F" thereof) and denies that Plaintiff is entitled to any relief whatsoever. Defendant therefore requests that the Complaint be dismissed with prejudice in its entirety.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint, and each claim for relief, fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

No misrepresentation, or false or misleading statement or omission was made by or on behalf of Defendant that directly or indirectly: (a) involved any material fact; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; (e) was made with any requisite level of scienter or intent to deceive; or (f) would operate as a fraud or deceit upon anyone.

THIRD AFFIRMATIVE DEFENSE

Defendant did not employ any device, scheme or artifice to defraud, including any that directly or indirectly: (a) involved any material fact; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; (e) was made with any requisite level of scienter or intent to deceive; or (f) would operate as a fraud or deceit upon anyone.

FOURTH AFFIRMATIVE DEFENSE

Defendant did not engage in any act, practice, course of business or transaction that operated as a fraud or deceit, including any that directly or indirectly: (a) involved any material fact; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; or (e) was made with any requisite level of scienter or intent to deceive.

FIFTH AFFIRMATIVE DEFENSE

Defendant did not obtain any money or property by any means that directly or indirectly: (a) involved in any way any untrue statement of material fact or omission to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; (e) was made with any requisite level of scienter or intent to deceive; or (f) would operate as a fraud or deceit upon anyone.

SIXTH AFFIRMATIVE DEFENSE

The statements alleged in the Complaint to have been made (or omitted), if any were in fact made (or omitted), had a basis in fact or reasonable basis.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because Defendant at all times acted in good faith, exercised reasonable due diligence, and because Defendant had after reasonable investigation, reasonable grounds to believe and did believe, at the time such statements were made (if any), that such statements were true and/or not misleading.

EIGHTH AFFIRMATIVE DEFENSE

The Complaint, and each claim for relief, fails to plead fraud with sufficient particularity.

NINTH AFFIRMATIVE DEFENSE

Defendant relied upon the advice of counsel.

TENTH AFFIRMATIVE DEFENSE

Defendant complied faithfully with all duties of disclosure to which he was subject, if any, and breached no duty of disclosure applicable to him.

ELEVENTH AFFIRMATIVE DEFENSE

The business judgment rule protects Defendant's alleged actions or failures to act and, thus, bars Plaintiff's claims.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's claim against Defendant for aiding and abetting violations of the securities laws fails as a matter of law because TKT did not violate any applicable law or statute; or, to the extent TKT's conduct did violate some law or statute, Defendant did not know or was not reckless in not knowing that TKT's conduct constituted such violation.

THIRTEENTH AFFIRMATIVE DEFENSE

If anyone suffered loss or damages, which Defendant denies, that loss or damages resulted from causes other than any alleged act or omission by Defendant.

FOURTEENTH AFFIRMATIVE DEFENSE

The fraud-on-the-market theory is not a basis of liability with respect to any of the claims in this action.

FIFTEENTH AFFIRMATIVE DEFENSE

The statements alleged in the Complaint to have been made, if any were in fact made, were forward-looking statements protected by applicable safe harbor provisions.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because TKT's public statements, registration statement/prospectus, prospectus supplements, and annual and quarterly filings with the SEC, sufficiently bespoke caution.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by applicable statutes of limitation and/or the doctrines of laches, and/or estoppel, and/or unclean hands and/or waiver.

EIGHTEENTH AFFIRMATIVE DEFENSE

Defendant is not liable as a controlling person within the meaning of Section 20(a) of the Exchange Act, or any rule or regulation promulgated thereunder, because he acted in good faith and did not directly or indirectly induce any acts or failures to act allegedly constituting a primary violation of any statute, or any rule or regulation promulgated thereunder.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because there was no culpable participation.

TWENTIETH AFFIRMATIVE DEFENSE

Defendant is entitled to payment of its attorneys' fees by Plaintiff pursuant to § 11(e) of the Securities Act of 1933, 15 U.S.C. § 77k(e).

TWENTY-FIRST AFFIRMATIVE DEFENSE

Defendant hereby gives notice that he intends to rely upon such other and further defenses as may become available or apparent during pretrial proceedings in this action and hereby reserves his rights to amend his answer and assert all such defenses.

WHEREFORE, Defendant respectfully requests that this Court:

- (1) Deny any and all relief requested by Plaintiff;
- (2) Dismiss the Complaint with prejudice and enter judgment in favor of Defendant on all Counts of the Complaint;
- (3) Award Defendant his attorneys' fees and costs incurred in the defense of this action; and
- (4) Award Defendant such further relief as the Court deems just and proper.

JURY DEMAND

Defendant demands a trial by jury on all issues so triable.

Dated: September 21, 2005 Boston, Massachusetts Respectfully submitted,

Thomas J. Dougherty (BBO#133300)

Justin J. Daniels (BBO #656118)

Cale P. Keable (BBO #651627)

SKADDEN, ARPS, SLATE,

MEAGHER & FLOM LLP

One Beacon Street

Boston, Massachusetts 02108

(617) 573-4800

Counsel for Defendant Richard F. Selden

CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that on September 21, 2005, I caused a true copy of the foregoing Defendant's Answer And Affirmative Defenses to be served by hand delivery upon Walter G. Ricciardi, United States Securities and Exchange Commission, 73 Tremont Street, Suite 600, Boston, Massachusetts 02108.

Dated: September 21, 2005

Justin J Daniels